

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 16, 2008 has been entered.

2. The Office action is responsive to an amendment filed September 16, 2008. Claims 1-12 are pending. Claim 1 has been amended. Claims 13-20 are cancelled.

### ***Response to Amendment***

3. The Affidavit under 37 CFR 1.132 filed September 16, 2008 is insufficient to overcome the rejection of claims 1-12 based in part upon US 6,367,973 to Yamaka as set forth in the last Office action because: although the Affidavit addresses the rejections over Sato (US 3,738,173) & Makita (US 5,340,215), the Affidavit fails to address the rejections over Yamaka at all even the Applicant at pg. 5 of the Remarks (dated September 16, 2008) seem to infer the opposite. Consequently, the Affidavit fails to make any statement regarding the disclosed "space" described in Exhibit I of the Remarks and thus fails to provide any support to the Applicant's arguments.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claim 1 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in the reply filed September 16, 2008. In that paper, at page 5, applicant has stated that "when mounted, the cover abuts up and provides a seal against the distal face (F) of the distal end (24)...as annotated by the Applicant [in the] provided Exhibit I"; wherein Exhibit I shows and describes a spacing between a flange (64) of the probe cover (32) and the distal face of the housing of the thermometer, and this statement indicates that the invention is different from what is defined in the claim(s) because the "heat sensing probe" as is defined in the claim at lines 2-3 extends from a distal end of the tympanic thermometer; as such, an underside of a distal end of the heat sensing probe would actually refer to the tip of the heat sensing probe rather than the distal end of the housing of the thermometer. Similarly, the claim defines the "heat sensing probe" as an element that is different and extends from the "tympanic thermometer," as such both terms cannot be used interchangeably in the claim. As such, "an underside of a distal end of the heat sensing probe" is not the same as "an underside of a distal end of the housing of the tympanic thermometer."

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 1 & 4-12** are rejected under 35 U.S.C. 103(a) as obvious over Yamaka (US 6,367,973) in view of Canfield et al. (US 6,186,959) further in view of Suszynski (US 4,863,281).

In regards to **claim 1**, Yamaka disclose(s) a tympanic thermometer 1 comprising:  
a heat sensing probe 6 defining a longitudinal axis and an outer surface  
extending from a distal end of the tympanic thermometer 1;

an ejection apparatus 7 including a button 81 and a finger 70 extending from the  
distal end of the tympanic thermometer 1 and the finger 70 being configured for  
movement along the outer surface of the probe 6 toward a distal end of the probe 6; and

a probe cover 10 being mountable to the distal end of the tympanic thermometer  
1, the mounted probe cover 10 defining an inner surface configured to engage the outer  
surface of the probe 6, and the mounted cover 10 conceals the finger 70 and the outer  
surface of the probe tip, the probe cover 10 including at least one proximal face  
projecting at the inner surface of the probe cover 10,

wherein the finger 70 is movable, to eject the probe cover 10, toward the distal  
end of the probe 6, the finger 70 moving along the outer surface of the probe 6 and  
along the inner surface of the probe cover 10, and further the probe cover is in contact  
with the proximal face at the inner surface of the probe cover 10 until the probe cover 10  
is released from the probe 6 (see abstract; see figs. 1-3 & 5; col. 4, lines 36-47; col. 10,  
lines 41-60).

In regards to **claim 5**, Yamaka disclose(s) a tympanic thermometer 1 wherein the  
finger 70 includes a tapered finger tip defining a distal strike face 73 (see fig. 3).

In regards to **claim 6**, Yamaka disclose(s) a tympanic thermometer 1 wherein the finger 70 is movable between a retracted position and an extended position (see figs. 2 & 5).

In regards to **claim 8**, Yamaka disclose(s) a tympanic thermometer 1 whereby the finger 70 is releasably fixable in a retracted position (see figs. 3 & 5).

In regards to **claims 10-11**, Yamaka disclose(s) a tympanic thermometer 1 includes a plurality of longitudinal ribs 18, each rib 18 having a transverse face having a substantially parallel orientation relative to the axis of the probe (see fig. 2; col. 6, lines 37-40).

*Yamaka discloses a tympanic thermometer 1, as disclosed above, that fails to explicitly teach a plurality of fingers, a longitudinal rib, protuberances or fingers for ejecting the probe cover.*

However, **Canfield et al.** teach that it is known to provide a thermometer with an ejection mechanism having a button and a spring; wherein the mechanism is biased to the extended position; wherein the mechanism is releasably fixable via a latch, whereby the latch includes a release button 15 that is engageable to release the at least one finger 13c from the retracted position (see figs. 23 & 23A-B; col. 34, lines 1-13, 18-26 & 35-46).

Moreover, **Suszynski** discloses teach that it is known to provide a tympanic thermometer comprising a heat sensing probe 17, an ejection apparatus 29 with a probe cover 19 that includes a flange 21, the flange 21 substantially abuts circumferentially an underside of a distal end of the heat sensing probe 17 and provides

a seal between the flange 21 and the distal end to help prevent patient excretions from collecting at the underside of the distal end (see figs. 1-3; col. 2, lines 52-65; col. 3, lines 17-21).

Applying the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

In regards to **claims 1, 7 & 9**, both Yamaka and Canfield et al. teach tympanic thermometers with ejection mechanisms that include a button that is orthogonal to the probe tip; since Yamaka teaches an ejection mechanism that moves a pushing member 70 perpendicularly from the ejection button 81 (see col. 7, lines 16-26) using a cam mechanism (see figs. 3 & 5; col. 9, lines 11-22) in order to mount the measuring switch 4 on the upper portion the back of the thermometer body as to concentrate the plurality of functional members in a small area thereby achieving a good operability of the thermometer (see col. 9, lines 22-35) and Canfield et al. teach that it is known to move a pushing member perpendicularly from an ejecting button 552 using a spring 562 (see figs. 23 & 23A-B; col. 34, lines 1-13, 18-26 & 35-46), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the thermometer of Yamaka to include a spring as taught by Canfield et al. in order to mount the measuring switch 4 on the upper portion of the back of the thermometer body

so as to concentrate the plurality of functional members in a small area thereby achieving a good operability of the thermometer.

Moreover, Yamaka teaches a tympanic thermometer wherein the probe cover (10), which is used for sanitation reasons (see col. 1, lines 38-43 & 50-56), abuts a surface of the ejection mechanism 7 sized to regulate the insertion depth of the probe 6 into the ear hole at a predetermined depth so as to permit body temperature measurement under optimum conditions and prevent damage done by the probe deep inside the ear (see col. 7, lines 53-67). Similarly, Canfield et al. teach a tympanic thermometer wherein the probe cover, which is used to prevent cross-contamination (see col. 11, lines 51-54 & 58-67; col. 12, lines 1-7) and seal the ear canal (see col. 18, lines 45-49), abuts a surface of the ejection mechanism that is sized to regulate the insertion depth of the probe into the ear hole at a predetermined depth (i.e. figs. 3C, 8B & 23B). Likewise, Suszynski teaches a tympanic thermometer wherein the probe cover, which is used to protect the patient and thermometer (see col. 2, lines 62-65), abuts a surface of the housing that is sized to regulate the insertion depth of the probe into the ear hole at a predetermined depth (see figs. 1-3). Since Suszynski teaches that the abutting surface sized to regulate the insertion depth of the probe may be the housing of the tympanic thermometer, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the tympanic thermometer of Yamaka as modified by Canfield et al. above, with a probe cover that abuts the housing of the tympanic thermometer as taught by Suszynski in order to achieve a thermometer wherein a surface of the housing regulates the insertion depth of the probe so as to

permit body temperature measurement under optimum conditions and prevent damage done by the probe deep inside the ear.

Even moreover, since all elements of the claim are known in the art; and since

a) one of ordinary skill in the art could have combined the teachings of Yamaka with those of Canfield et al. and Suszynski as suggested in the rejections supra by known methods,

b) in the combination, each element (i.e. tympanic thermometer of Yamaka, the spring/latch system of Canfield et al. and the housing- abutting characteristic of the probe cover of Suszynski) in the combination would have performed the same function as it did separately; and,

c) one of ordinary skill in the art would have recognized that the results of the combination were predictable,

The Examiner submits that combining prior art elements according known methods to yield predictable results has recently been held to be obvious (see KSR International Co. v. Teleflex Inc., 550 U.S.---, 82 USPQ2d 1385 (2007)).

In regards to **claim 4**, since Yamaka teaches a conical pushing member 70 that applies a pushing force circumferentially against the inner surface of probe cover; wherein the ejection apparatus and probe cover are substantially circumferentially symmetrical, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the thermometer of Yamaka as modified by Canfield et al. and Suszynski above to include a plurality of circumferentially- arranged,

tapered fingers, as claimed, in order to apply a conical pushing force circumferentially against the inner surface of probe cover.

Similarly, in regards to **claim 12**, since Yamaka teaches a circumferential distal strike face on the probe cover so as to apply a circumferential pushing force on the distal strike face to eject the probe cover; wherein the ejection apparatus and probe cover are substantially circumferentially symmetrical, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the thermometer of Yamaka as modified by Canfield et al. and Suszynski above to include a plurality of circumferentially-symmetrical distal strike faces as claimed, in order to apply a circumferentially symmetrical pushing force on the distal strike face to eject the probe cover.

8. **Claims 2-3** are rejected under 35 U.S.C. 103(a) as obvious over Yamaka ('973) in view of Canfield et al. ('959), Suszynski ('281), and further in view of Makita et al. (US 5,340,215).

*Yamaka as modified by Canfield et al. and Suszynski teach a tympanic thermometer, as described above, that fails to explicitly teach a groove and a protuberance.*

However, **Makita et al.** disclose a tympanic thermometer including a probe 9 having an outer surface of the probe that defines a groove, transversely oriented relative to the longitudinal axis, which is configured to receive a portion of the probe cover 9 for releasably retaining the probe cover 9 with the probe; (see figs. 1-6).



In regards to **claim 2**, since Yamaka teaches a protuberance/annular groove mechanism for fixing the probe cover 10 with the probe 6 without fail (see figs. 2-3; see col. 5, lines 46-57), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the thermometer of Yamaka as modified by Canfield et al. and Suszynski above to include a groove on the probe and protuberance on the probe cover as taught by Makita et al. in order to fix the probe cover with the probe without fail.

In regards to **claim 3**, since Yamaka teaches a tympanic thermometer comprising a plurality of engaging mechanisms (i.e. protuberance/annular groove mechanisms) (see col. 6, lines 20-26) for fixing the probe cover 10 with the probe 6 without fail (see figs. 2-3; see col. 5, lines 46-57), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to modify the thermometer of Yamaka as modified by Canfield et al., Suszynski and Makita et al. above to include a plurality of grooves on the probe and protuberances on the probe cover as claimed in order to more securely fix the probe cover with the probe without fail.

### ***Response to Arguments***

9. Applicant's arguments filed September 16, 2008 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to achieve a cover that abuts the housing of the device of Yamaka to protect the ejection mechanism from contamination. This argument has been considered but has not been deemed persuasive.

In response to the Applicant's argument, the Examiner respectfully traverses. First, the Examiner notes that in all prior arts of record having a probe cover, the probe cover serves the same function of protecting the probe during use from contamination. Second, the Examiner notes that Yamaka, as Applicant clearly admits in the Remarks at pgs. 6-7, teaches a device wherein the probe cover abuts the ejection mechanism so as to control insertion depth. As such, it is self-evident that the device of Yamaka cannot be inserted past the ejection mechanism; in other words, the proximal end of the ejection mechanism needs no protection from cross-contamination since it does not come into contact with the patients. Similarly, what's apparent in the prior art of Yamaka is the fact that Yamaka's ejection mechanism limits overpenetration of the probe. In a similar manner, Suszynski teaches a device wherein the insertion depth is controlled, not by the ejection mechanism but by the housing itself such that the probe cover abuts the housing. As such, it transpires that either one of the ejection mechanism and the housing of the tympanic thermometer can protect from overpenetration of the probe; for example, by providing an abutting face having a surface and cross-sectional area that is large enough to abut against a "region of the vicinity of the entrance to the earhole" without penetrating the ear "so as to regulate the insertion depth of the probe into the earhole at a predetermined depth." Consequently, the probe cover would need only cover the portion (i.e. probe) of the device that comes in contact with the inside of the ear thereby abutting any surface (i.e. whether from the ejection mechanism or housing of the tympanic thermometer) that abuts the underside of the proximal end of the probe. As such, the Examiner submits that it would have been obvious to modify Yamaka (i.e.

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by reducing the diameters of the ejection mechanism and probe cover such that it [the ejection mechanism] can and does at least partially penetrate the ear during use; wherein the housing would limit overpenetration of the probe as taught in Suszynski. Because the ejection mechanism now at least partially penetrates the ear, it would need to be protected by the probe cover, which would thereby abut the distal face of the housing of Yamaka.

In view of the foregoing, the rejections over Yamaka are maintained.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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